

### **Remarks and Arguments**

Claims 62-63, 65-66, 70-73, 75-79, 82, 87-90, 99-100, 102-110, 113, 118-125, 131 and 133 are pending. Claims 62, 65, 66, 73, 82, 90, 99, 100, 113, 121, 122, 131, and 133 are amended in response to the Examiner's comments. Claims 134-152 are newly added. Claims 70-72 are newly canceled. Applicants reserve the right to present additional subject matter in one or more continuation or divisional applications. No new matter has been added by way of any of these amendments or additional claims.

### **Obviousness-type double patenting rejection**

The Examiner has rejected claims 62-63, 65-66, 70-73, 75-79, 82, 87-90, 99-100, 102-110, 113, 118-125, 131 and 133 as unpatentable over U.S. 11/641,644. Applicants respectfully note that U.S. 11/641,644 is now abandoned and thus request withdrawal of this rejection.

### **Rejections under 35 U.S.C. §102(b)/ 102(e)**

The Examiner has again rejected claims 62-63, 65-66, 75-76, 82, 87-90, 99-100, 106, 113, 118-122, 131 and 133 under 35 U.S.C §102(b) and 35 U.S.C §102(e) as anticipated by Campbell, et al. (WO 97/07669) and US Patent No. 6,147,276.

Applicants submit that (i) Campbell is non-enabled and (ii) that the non-enablement of Campbell does not dictate the non-enablement of the claimed invention, as the Examiner suggests.

### **Enablement**

As the Examiner is aware, the standard for determining whether a given disclosure meets the enablement requirement is whether the experimentation needed to practice the invention is undue or unreasonable. See *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916). Factors for determining undue experimentation include: (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). See also MPEP 2164.01(a). Merely conclusory statements are insufficient to

support an enablement rejection and must be based on evidence, not mere opinion. MPEP § 2164.05.

**(1) Campbell is Non-Enabled**

The Applicants understand that the patentee bears the burden of proving the non-enablement of the cited reference. To that end, Applicants note their arguments on the non-enablement of Campbell in the responses dated March 18, 2009 and October 14, 2009. The Applicants provide a brief summary of those arguments here.

Campbell was the first to produce a viable animal using somatic cell nuclear transfer. Somatic cell nuclear transfer, of course, is not the Applicants' invention. Rather, the Applicants' invention is a method of producing a viable animal using somatic cell nuclear transfer, *where the somatic cells have been genetically modified*.

Campbell (and others) spoke to the desirability of the Applicants' invention. But there is an important difference between describing the desirability of a given invention or even speculating about how one of skill in the art might approach the inventive task and actually providing a disclosure sufficient to permit one of skill in the art to make and use that invention. For the reasons argued previously, Applicants maintain that Campbell did not provide a disclosure sufficient to permit one of skill in the art to make and use the claimed invention and is therefore non-enabled. And that belief is not just the Applicants', but the belief of others working in the field -- as evidenced by the commentary published in the esteemed journal *Nature*, which stated that until the present invention, "no one had shown that it would be possible" to produce viable animals using genetically modified somatic cells in nuclear transfer. See *Nature* (2000) 405: 1004-1005.

To date, the Examiner has not responded to the Applicants' arguments regarding the non-enablement of Campbell other than to state that Campbell "teaches exactly what is claimed." Rather, the Examiner's has focused on the second point, i.e., that the Applicants' position on the non-enablement of Campbell dictates the non-enablement of the Applicants' claims.

**(ii) The Non-Enablement of Campbell Does Not Dictate the Applicants' Non-Enablement**

The Examiner has not specifically made an enablement rejection under 35 U.S.C §112. In fact, *the Applicants have overcome all prior enablement rejections*. Rather, the Examiner's only suggestion that the claimed invention might be non-enabled is in response to the Applicants' statement that Campbell is non-enabled. The Examiner specifically ties the enablement of the claimed invention to the enablement of the prior art reference, arguing that "there is nothing that distinguishes the claimed invention from that which is taught in Campbell."

Applicants submit that consistent with the Wands factors, *a later-filed disclosure can enable a claimed invention even if the same disclosure - earlier filed- would not have*. As stated in MPEP § 2164.05(a):

The state of the art for a given technology is not static in time. It is entirely possible that a disclosure filed on January 2, 1990, would not have been enabled. However, if the same disclosure had been filed on January 2, 1996, it might have enabled the claims. Therefore, the state of the prior art must be evaluated for each application based on its filing date.

To paraphrase the wording of the MPEP - changing only the dates - it is entirely possible that a disclosure filed on August 31, 1995 (Campbell) would not have been enabled but that the *same* disclosure filed April 9, 1999 (the present application) might have enabled the claims.

Applicants note several other considerations under Wands that differ between Campbell and the claimed invention. The state of the prior art, for example, differs at the time of each application- which (as noted above) were filed more than four years apart<sup>1</sup>. The amount of guidance provided by the inventor (in fact, the present application is not the same disclosure) and the presence of a working example (i.e., an example based on work actually performed- characteristic of pending application), provide other examples<sup>2</sup>. All of these factors, although not intended to be exhaustive, are important considerations under Wands and *they differ between the two applications*. Again, because enablement is determined with reference to Wands and

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<sup>1</sup> There can be little doubt that the art of nuclear transfer was in its infancy in 1995, given that nuclear transfer was in fact- the invention in Campbell.

<sup>2</sup> While the existence of a working example is not determinative of enablement, the lack of a working example, is a factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.02. The Examiner has previously described the present technology as unpredictable.

because the two applications differ with respect to the same, Applicants respectfully submit that *the non-enablement of Campbell does not dictate the non-enablement of the claimed invention.*

In at least several places, the Examiner suggests that the Applicants amend the claims to “be enabled and distinguished from the prior art”. In fact, there is no pending enablement rejection. Moreover, the fact that the present rejection is not formally an enablement rejection should not be a reason to permit conclusory statements relating to enablement of the claimed invention that operate to discourage the Applicants from arguing the enablement-based limitations of the prior art and/or to force additional claim amendments- *particularly when prior enablement rejections have been overcome*. The Applicants shouldn’t have to “pick their poison,” as it were. Rather, the claimed invention is enabled and the prior art is not.

#### **Rejections under 35 U.S.C. § 103(a)**

The Examiner has again rejected claims 62-63, 65-66, 70-73, 75-79, 82, 87-90, 99-100, 102-110, 113, 118-125, 131 and 133 under 35 U.S.C §103(a) as obvious over Campbell, et al. (WO 97/07669) in view of one of the following: U.S. 5,849,991; WO94/02602; U.S. 6,013,857; or Bedalov (J. Biological Chem. 269(7):4903-4909, 1994) when taken with Rossert (J. Cell Biol. 129(5): 1421-1432, 1995). Applicants respectfully traverse this rejection.

Applicants submit that Campbell fails as a referenced under §103(a) for the same reasons it fails under §102, because it is non-enabled. As such it does not provide proper support for a § 103(a) rejection in combination with any of the additional cited references.

#### **Conclusions**

The Applicants understand that present rejection is prior art based, i.e., Campbell under §102 and § 103. The Applicants submit that the Campbell reference is non-enabled. The Examiner has suggested that the Applicant cannot challenge the enablement of a prior art reference without comprising the Applicants’ own enablement. However, as discussed above, one does not dictate the other and the Applicants note that all prior enablement rejections have been overcome.

Applicants believe no additional fees beyond those for an Extension of Time and an RCE are required with this response. Should the Examiner determine otherwise, the Commissioner is

authorized to charge any underpayment or credit any overpayment of fees to Deposit Account No. 11-0980.

Respectfully submitted,

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